SEP 26 2000

K001970

510 (K) Summary

Pride Mobility Products, Inc.
510 (K) Premarket Notification
JET 1

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Pride Mobility Products, Inc.
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-4849

Contact Person: Gene Kulon
Official Correspondent
Date Prepared: 05-15-00

Name of Device and Name / Address of Sponsor:

JET 1

Pride Mobility Products, Inc.
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-4849

Common or Usual Name:
Six Wheel Power Base Unit

Classification Name:
Power Wheel Chair

Comparison to Predicate Devices:

The product, which is substantially equivalent to the JET 1, is the SC900 (Jazzy 1100) (K945936), they are both are Joystick controlled, with onboard batteries and battery charger. They are both mid-wheel drive power chairs with rear caster and front anti-tip wheels. All safety features are equivelant.

Device Description:

The Pride Jet 1 model mid-wheeled drive powered wheelchairs are battery powered, motor driven devices with the intended function and use of providing mobility for those

persons limited to a seated position that have the capability to operate a powered wheelchair. A Dynamic DL joystick and controller are used to operate the Jet 1. It is powered by two size NF-22, 12 VDC batteries and has a range of up to 25 miles on a full charge. The base of the chair is made of welded steel construction. Seating material meets California 117 standards for fire retardancy.

Intended Use:

The intended use of the JET 1 is to provide mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

Discussion of non-clinical tests performed for determinations of substantial equivalence are as follows:

ANSI/RESNA WC/02 1991 Wheelchair Standard for Static Stability Testing
ANSI/RESNA WC/02 1991 Wheelchair Standard for Dynamic Stability Testing
ANSI/RESNA WC/Vol. 2-1998 Wheelchair Standard for EMC Testing.

Discussion of Clinical Tests Performed:

N/A

Conclusions:

The Jet 1 has the same intended use and similar technological characteristics as the Jazzy. Moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Jet 1 device is substantially equivalent to the predicate device. All software used on the Jet 1 is Y2K Compliant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2000

Mr. Gene Kulon
Official Correspondent for
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pennsylvania 18643-2694

Re: K001970
Trade Name: Jet 1 Powered Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: June 27, 2000
Received: June 28, 2000

Dear Mr. Kulon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K001970

Device Name: Jet 1 Powered Wheelchair

Indications For Use:

The intended use of the Jet 1 is to provide mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001970

Prescription Use ____ **(Per 21 CFR 801.109)** **OR** **Over-The-Counter Use** Y **(Optional Format 1-2-96)**